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Fouad El-Baroudi

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,250	<b>Applicant(s)</b> EL-BAROUDI, FOUAD	
	<b>Examiner</b> Michael Borin	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/01/2005</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### **Status of Claims**

Claims 1-9 are pending.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement filed 07/01/2005 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claim 1, step of "applying at least one determined constraint": the claim lacks internal antecedent basis as the preceding part of the claim does not address determining any constraints.

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B. Claim 1, step of determining analytic function: First, it is not clear what is encompassed by “analytic function” – there is no active step addressing it, and it is not clear what is encompassed by such definition. Second, it is not clear what “interaction parameters” are being addressed; the preceding part of the claim does not address any “interaction parameters”.

Clarification via clearer language is requested.

C. Claim 3 addresses “The step of representing the result of a constraint” of claim 1. However, claim 1 does not address such a step of “To representing the result of a constraint”

Clarification via clearer language is requested.

D. Claim 4: The claims addresses connecting elements that have an effect on the interaction parameters. It is not clear which “elements” are meant and how they are connected.

### ***Claim Rejections - 35 U.S.C. § 101***

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-9 are drawn to method of simulation of bone joints. The claims do not recite any physical transformation step, nor they recite a tie to another category of invention.

To qualify as a statutory process, the claims should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state or thing. In the instant case, claims do not recite any physical transformation step. Further, there is no step in the claims that recites a tie to another category of invention. Therefore, the claims are drawn to non-statutory subject matter for failing to recite a step that ties the method to another category of invention.

A claimed process is patent-eligible under § 101 if it is tied to a particular machine or apparatus, or it transforms a particular article into a different state or thing. Thus, the machine-or-transformation test is a two-branched inquiry: an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. See *In re Bilski* (Fed. Cir., October 30, 2008). The use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility. Further, the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.

The claims are directed to method wherein the data reflecting "rigid body" positions are being converted, compared and processed. Applicants' method is neither tied to a particular machine or apparatus, nor it transforms a particular article into a different state or thing. Thus, the claims fail the machine-or-transformation test and is not drawn to patent-eligible subject matter.

***Claim Rejections - 35 USC § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Aouni-Ateshian (US 6,161,080)

The instant method is directed to method of biomechanical simulation of bone joints in a patient comprising

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- Recording in a reference position of a three-dimensional digital model, at least partly represented by rigid bodies connected by joints
- Personalizing the geometry of the model using data specific to a patient
- Personalizing the digital model, and
- determining analytic functions to approximate interaction parameters to reproduce the measured relative positions for each pair of rigid bodies.

The personalizing is achieved by

particularizing interaction parameters of each joint as observed in the patient by

-building up a digital table containing the relative positions of each rigid body by

acquiring the positions in space of at least a part of the rigid bodies, and making an interpolation to determine the calculated position of other rigid bodies

- applying at least one determined constraint on the patient and acquiring information about the resultant general equilibrium position of the patient

6,161,080 teaches method of generating a three dimensional representation of anatomical joints comprising the steps by acquiring three-dimensional anatomically representative data of two or more movable bodies of a selected joint, selecting one or more link types responsive to said representative data of the bodies, and selecting link characteristics responsive to each selected link type. See claim 2, for example:

2. A method of generating a three dimensional representation of more than one anatomical joint on an output device, wherein said representation comprises two or more movable bodies and one or more links associated with the selected number of joints, comprising the steps of:

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acquiring anatomically representative data of two or more movable bodies of a selected number of joints;  
selecting one or more link types responsive to said representative data of the bodies for each of the selected number of joints;  
selecting link characteristics responsive to each selected link type;  
generating an equilibrium condition responsive to interaction between the bodies and the links;  
and  
displaying a three dimensional representation of said anatomical joints on the output device responsive to the data generated from the equilibrium condition for the selected number of joints.

The model includes both geometric (see col.3, lines 40-56, col. 4, col. 32, lines 34-50) and stiffness parameters (e.g., col. 3, lines 16-40). Further, the model combines multiple bodies and reflects their relative positions (see, e.g., col. 2, bottom, col.34, lines 11+). Further, the model addresses multiple constraints – see claim 6 and col. 29, section 5.2.10. The data generated from the equilibrium condition responsive to interaction between the bodies and links predict the kinematic orientation, the kinematic position, the contact force, and the contact area of the movable bodies and links (claim 3)

With regard to the steps directed to “personalizing” of the model, ‘080 patent teaches:

Once the patient joint geometry is obtained, a patient specific model can be constructed and analyzed to suggest a best physical therapy program or a surgical procedure. One of the advantages of the multibody model is its rapid convergence by using an efficient analytical Jacobian formulation and contact calculation. It also provides sophisticated interactive graphics to view the three-dimensional model, and menu-driven windows to easily modify model parameters. Through all these features, the model allows a user to interactively modify different geometric and structural parameters, and observe the effects of these parameters almost immediately. The user can explore various parameters efficiently and quantify their mechanical effects on the joint.

With regard to the last method step of claim 1, first, ‘080 patent teaches that the geometry of large number of points on the joint surfaces are approximated by polynomials in space (col. 3, lines 40-56). Further, the patent teaches reproduction of the measured positions – see claim 13, last step.



With regard to claims 2,4,6,9 the model includes both geometric (see col.3, lines 40-56, col. 4, col. 32, lines 34-50) and stiffness parameters (e.g., col. 3, lines 16-40).

Geometric entities included bone geometry and articular surface geometry, as well as insertion locations for ligaments and tendons (col. 32 , lines 34+). Further, with regard to claim 9, the model addresses insertion elements; see sections 5.2.4, 5.2.5, 6.2.

Further, with regard to claim 5, “personalization” step involves acquiring and analyzing image information ; see col.32-33, for example.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed or fully envisioned by the teaching of the reference cited above

Alternatively, it appears that certain permutation of embodiments (or “models”) addressed in ‘080 patent are described as different models. See col. 3-4, for example. If so, applying the KSR standard of obviousness (*KSR Int’l* 7, 127 S. Ct. at 1740) the combination of different embodiments would be obvious to one skilled in the art as it represents a combination of known elements which yield the predictable result of comprehensive and adjustable simulation of bone joints.

#### ***Prior art made of record***

The prior art made of record and not relied upon is considered pertinent to applicant’s disclosure

Lynch et al. (5,835,693) teach interactive system for simulation and display of multi-body systems in three dimensions.

Sarin et al. ( US 20040097952 ) teach method of selecting implant modules and/or adjustments based upon digital model of adjustable hip implant system, a desired post-operative hip geometry, and a set of available modular implant components selectable measurements.

Xia et al. teaches three-dimensional virtual reality surgical planning and simulation workbench for orthognathic surgery.

***Conclusion.***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./  
Primary Examiner, Art Unit 1631

mlb